



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of

Glocker

Atty. Ref.: 2590-134; Confirmation No. 8800

Appl. No. 10/552,074

TC/A.U. 3736

Filed: November 17, 2005

Examiner: Sean Patrick Dougherty

For: Method For Measuring Pressures Deriving From Leakage Current

\* \* \* \* \*

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**RULE 132 DECLARATION**

I, **André Roland**, hereby declare as follows:

1. I am a citizen of Switzerland, and I reside at Jouxkens-Mézery. I am managing partner at ANDRE ROLAND S.A., which is located in Lausanne, Switzerland.
2. I have a degree in Physics and a certificate in Human Physiology. I have been employed in the medical industry for 3 years, European patent examiner in the field of medical devices during 5 years and patent attorney for 11 years. My work experience as patent attorney is frequently related to medical devices.
3. I have read and understand the subject U.S. patent application and the amended claims attached to this Declaration. I have also read the USPTO's Office Action dated August 4, 2008. I have also read and understand the references cited in the Office Action, i.e., Knoll (USP 6450972 B!) and Nicholas (USP 5433708 A).

4. I am not aware of any prior art that discloses or suggests the invention covered by the attached claims.

5. In the Final Office Action, claims 1-7, 9-17 and 19-20 stand rejected as allegedly being obvious over Knoll in view of Nicholas. However, neither of these references disclose or suggest the use or employment of the claimed "leakage current." The following information on "leakage current" is submitted for the USPTO's consideration and understanding of the claimed invention.

6. The Knoll reference is limited to the measurement of the electrical capacity, as admitted by the examiner. The Knoll device is not made for measuring a current or leakage current because normally there is no current flowing in the Knoll device. Ideally, as mentioned in the Wikipedia definition below, the current should be zero. As a result, there is no disclosure, suggestion or incentive in the Knoll to replace Knoll's capacity measurement by the measurement of a parameter, i.e. the current, which is known to be zero.

7. With respect to the claimed invention, it has been discovered that the capacitive impedance between the saline solution and the electrode may change. A current, i.e. leakage current, is therefore generated. Measuring the leakage current provides an improved determination of the pressure profiles, as discussed in the application.

8. The following definition and explanation is taken from Wikipedia, as known to those of ordinary skill in the art of the claimed invention:

In electronics, leakage refers to a gradual loss of energy from a charged capacitor. It is primarily caused by electronic devices attached to the capacitors, such as transistors or diodes, which conduct a small amount of

current even when they are turned off. Even though this off current is an order of magnitude less than the current through the device when it is on, the current still slowly discharges the capacitor. Another contributor to leakage from a capacitor is from the undesired imperfection of some dielectric materials used in capacitors, also known as *dielectric leakage*. It is a result of the dielectric material not being a perfect insulator and having some non-zero conductivity, allowing a *leakage current* to flow, slowly discharging the capacitor.

Leakage current is also any current that flows when the ideal current is zero. Such is the case in electronic assemblies when they are in standby, disabled, or "sleep" mode. These devices can draw one or two microamperes while in their quiescent state compared to hundreds or thousands of milliamperes while in full operation. These leakage currents are becoming a significant factor to portable device manufacturers because of their undesirable effect on battery run time for the consumer.

9. The claimed invention's measurement of leakage current is different than measurement of electrical resistance, capacitance, direct current or alternating current disclosed and taught in Knoll and is not "leakage current" in medical applications as the Supervisory Patent Examiner mentioned during the Interview. The claimed invention measures leakage current and does not measure capacitance in the classical way by voltage measurements.

10. The claimed invention includes the key features of "detecting" "the leakage current" and "transferring the leakage current" "to a converter" to "convert the leakage current" "into corresponding pressure values ..." Knoll no where discloses or suggests these features or the use of any leakage current. As noted above, Knoll does not use leakage current. Instead, and in contrast to the claimed invention, the Knoll reference is based on capacitance measurements to reflect pressure values. This difference of parameters is fundamental. The subject application itself discusses the differences. See, e.g., the paragraph bridging pages 6-7 of the subject application. As correctly

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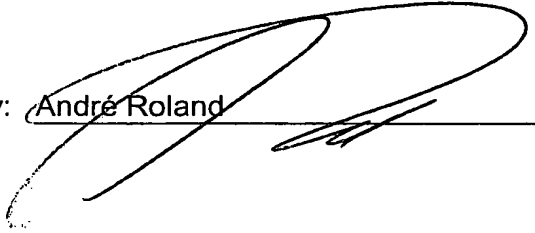
stated in the application, the use of leakage current instead of capacitance provides a more accurate pressure value. This approach is new and non obvious.

11. For at least the foregoing reasons and facts, the two cited prior art references do not disclose or suggest the claimed invention (as set forth in the attached amended claims).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: January 31, 2009

By: André Roland



**Amended Claims**

1. (Currently Amended) A method for performing pressure measurements in a mammal by means of a pressure profile sensors technique, which comprises

a) introducing into the mammal a catheter lumen having at least a portion of its wall which is sufficiently flexible to be deflected by external pressure;

b) introducing progressively into the catheter lumen an electrically conductive liquid substance while applying simultaneously to ~~it~~ the electrically conductive liquid substance an alternative current and mechanical oscillations;

c) detecting by means of an electrode placed at an external surface of the mammal a leakage current induced by the liquid substance traveling through the catheter;

d) transferring the leakage current thus recorded to a converter suitable to convert the leakage current provided thereto into corresponding pressure values; and

e) displaying the pressure values as such, or as a function of a measurement location or measurement period or both, to afford corresponding pressure profiles.

2. (Previously Presented) The method of claim 1, wherein the alternative current is a low voltage and high frequency current and wherein the mechanical oscillations have controlled amplitude and frequency.

3. (Previously Presented) The method according to claim 1, wherein the catheter is made of innocuous polymer plastic material.

4. (Previously Presented) The method according to claim 1, wherein the catheter is a single lumen or a multi-lumen catheter.

5. (Previously Presented) The method according to claim 1, wherein the electrically conductive liquid substance is an aqueous liquid.

6. (Previously Presented) The method according to claim 1, wherein the electrically conductive liquid substance is progressing step-by-step through the catheter lumen.

7. (Previously Presented) The method according claim 1, wherein the alternative current voltage applied to the electrically conductive liquid substance is between about 500 mV and about 6 V.

8. (Previously Presented) The method according to claim 1, wherein the alternative current frequency applied to the electrically conductive liquid substance is between about 60 and 130 kHz.

9. (Previously Presented) The method according to claim 1, wherein the mechanical oscillations applied to the electrically conductive liquid substance have a maximum amplitude of about 4 mm and a maximum frequency of about 15 Hz.

10. (Currently Amended) A method of performing real time pressure profile measurements or performing~~Performing~~ pressure measurements in mammal body tracts or cavities, or blood vessels using the method of claim 4 comprising:

a) introducing into the mammal a catheter lumen having at least a portion of its wall which is sufficiently flexible to be deflected by external pressure;

b) introducing progressively into the catheter lumen an electrically conductive liquid substance while applying simultaneously to the electrically conductive liquid substance an alternative current and mechanical oscillations;

c) detecting by means of an electrode placed at an external surface of the mammal a leakage current induced by the liquid substance traveling through the catheter;

d) transferring the leakage current thus recorded to a converter suitable to convert the leakage current provided thereto into corresponding pressure values; and

e) displaying the pressure values as such, or as a function of a measurement location or measurement period or both, to afford corresponding pressure profiles.

11. (Cancelled).

12. (Currently Amended) ~~A method for performing~~ Performing ex-temporaneum pressure measurements using a method for performing pressure measurements in a mammal by means of a pressure profile sensors technique, comprising:

a) introducing into the mammal a catheter lumen having at least a portion of its wall which is sufficiently flexible to be deflected by external pressure;

b) introducing progressively into the catheter lumen an electrically conductive liquid substance while applying simultaneously to the electrically conductive liquid substance an alternative current and mechanical oscillations;

c) detecting by means of an electrode placed at an external surface of the mammal a leakage current induced by the liquid substance traveling through the catheter;

d) transferring the leakage current thus recorded to a converter suitable to convert the leakage current provided thereto into corresponding pressure values; and  
and

e) displaying the pressure values as such, or as a function of a measurement location or measurement period or both, to afford corresponding pressure profiles the method of claim 1 by

and further comprising:

recording the pressure values provided by the converter and by displaying them at a time different from that of the leakage current ~~recording~~ thus recorded.

13. (Currently Amended) ~~An apparatus for performing the method of claim 1 a~~ method for performing pressure measurements in a mammal by means of a pressure profile sensors technique, comprising:

a) introducing into the mammal a catheter lumen having at least a portion of its wall which is sufficiently flexible to be deflected by external pressure;

b) introducing progressively into the catheter lumen an electrically conductive liquid substance while applying simultaneously to the electrically conductive liquid substance an alternative current and mechanical oscillations;

c) detecting by means of an electrode placed at an external surface of the mammal a leakage current induced by the liquid substance traveling through the catheter;

d) transferring the leakage current thus recorded to a converter suitable to convert the leakage current provided thereto into corresponding pressure values; and

e) displaying the pressure values as such, or as a function of a measurement location or measurement period or both, to afford corresponding pressure profiles,

and which further comprises:

a source of an electrically conductive liquid substance connected to an alternative current source;

a peristaltic pumping means fitted directly to the source of liquid substance;

a mechanical oscillation means connected downwards to down stream from the peristaltic pumping means;

an electrode capable of being placed at the external surface of the mammal for recording and then transferring a detected leakage current to a converter;

a converter suitable for deriving pressure values from the leakage current parameters which have been transferred thereto; and

a means suitable to display pressure values as such, or as a function of the measurement location or measurement period or both.

14. (Previously Presented) Method according to claim 9, wherein the mechanical oscillations applied to the electrically conductive liquid substance have an amplitude of about 2 mm and a frequency of about 10 Hz .

15. (Previously Presented) The method according to claim 3, wherein the catheter is made of non-conductive innocuous polymer plastic material.

16. (Previously Presented) The method according to claim 5, wherein the electrically conductive liquid substance is a saline solution.

17. (Previously Presented) The method according claim 7, wherein the alternative current voltage applied to the electrically conductive liquid substance is between about 1 and about 4 V.

18. (Previously Presented) The method according to claim 8, wherein the alternative current frequency applied to the electrically conductive liquid substance is between about 80 and 120 kHz.

19. (Currently Amended) The method according to claim 10, wherein the  
~~Performing pressure profile measurements in mammal body tracts or cavities~~  
~~comprising comprise a lung, esophagus, stomach, intestine, urinary tract or bladder, or~~  
~~blood vessels, using the method of claim 10.~~

20. (Cancelled).